K082596

SEP 23 2008

510(k) Summary

Date:	May 12, 2008
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact: (714)730-5000	Paul Biggins, Regulatory Affairs Specialist,
Establishment Registration Number:	2020563
Device Proprietary Name:	USWS-900A; UltraExtend Ultrasound WorkStation Package
Common Name:	System, Image Processing, Radiological
Regulatory Class:	II [21CFR820.2050, .1560, .1550]
Performance Standard:	None
Predicate Device(s):	TomTec Image-Arena Applications [k071232] Toshiba, SSH-880CV, Artida Diagnostic Ultrasound System [k080160]
Reason for Submission	New Device

Description of this Device:
The USWS-900A is a software package that may be applied to an existing workstation that is capable of receiving 2D, M-mode, spectral Doppler and 3D data sets via DICOM. This software consists of measurement packages that were cleared on the predicate device, SSH-880CV Artida Diagnostic Ultrasound System.

Summary of Intended Uses:
The intended use is for displaying and analyzing ultrasound images for medical diagnosis in cardiac and general examinations.

Safety and Effectiveness Concerns:
This software package is designed and manufactured in compliance with the Quality System Regulation. This device does not offer new indications or functions that have not

been cleared via the predicate devices, nor does it offer functions that are not already available through 510(k) cleared devices that are commercially available in the U.S.

Substantial Equivalence:
This software package provides information to the user that is similar to that which is provided by the predicate devices. The information is obtained in a manner that is similar to the predicate devices, or in a manner that is a combination of the predicate devices. Additionally, the indications for use and intended uses are identical to the predicate devices. There are no new indications for use that are not already available in devices already marketed in the U.S.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2008

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082596
Trade/Device Name: USWS-900A, UltraExtend
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 5, 2008
Received: September 8, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: USWS-900A, UltraExtend

Indications for Use:

The USWS-900A Ultrasound Workstation, when used by a qualified physician, is intended for displaying and analyzing ultrasound images for medical diagnosis in cardiac and general examinations.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082596